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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,438	11/14/2003	Douglas G. Evans	KN P 0131	9636

7590

02/03/2006

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EXAMINER
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BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 02/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/713,438

Applicant(s)

EVANS ET AL.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 36-71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 25, 2005 has been entered.

### ***Response to Amendment***

2. Applicants' cancellation of claims 1-35 in the reply filed on November 25, 2005 is acknowledged.
3. Applicants' addition of claims 36-71 in the reply filed on November 25, 2005 is acknowledged.
4. The two Declarations under 37 CFR 1.132 filed November 25, 2005 are sufficient to overcome the rejection of claims based upon Yamamoto et al. (US PG Pub NO. 2002/0183855 A1).
5. The Examiner respectfully requests Applicants to provide: (i) the chemical process/method used on the instant application for extracting native/natural collagen fibers from corium or bovine hide; and (ii) the chemical process/method used on the instant application for incorporating/adding minerals to the matrix. Said methods could not be found in the instant application.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 36, 37, 39, 43-50, 59-61, and 68 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nigam (US 4,948,540; cited in Applicants' IDS).

Nigam discloses a conformable (see Abstract), multi-phasic implant, said implant comprising/consisting of a plastically deformable (the matrix is plastically deformed into a sheet), tissue conductive matrix, said matrix comprising/consisting of two phases/components, wherein a first phase/component of said matrix comprises/consists of native insoluble collagen fibers (see column 2), and a second phase/component of said matrix comprises/consists of flowable collagen gel (e.g., soluble collagen; see column 2), said implant having a consistency of putty prior to implantation (the slurry, while being subjected to freeze-drying, will have a slurry/paste consistency before it will be implanted), and remaining at least somewhat compliant after implantation (see Abstract; see entire document). The matrix further comprises a beneficial agent (see column 2). The ratio of soluble collagen to native/natural insoluble collagen fibers is maintained in the range of 1:20 to 10:1 (see column 4, lines 24-27).

8. Claims 36, 37, 39-50, 59-61, and 69-71 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Devore et al. (US 6,183,498).

Devore et al. disclose a conformable (it is capable of being conformed to the repair site), multi-phasic implant, said implant comprising/consisting of a plastically deformable ("*capable of*

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*being plastically deformed*”: according to column 8, lines 56-59, the matrix includes plasticizers; also, the matrix is disclosed as polymerizable, and because of the intended use it will plastically deform), tissue conductive matrix, said matrix comprising/consisting of two phases/components, wherein a first phase/component of said matrix comprises/consists of native insoluble collagen fibers (see column 6, lines 1-7; see claim 10), and a second phase/component of said matrix comprises/consists of flowable collagen gel (e.g., soluble collagen; see entire document), said implant having a consistency of putty (the matrix is disclosed as viscous and malleable; see entire document) prior to implantation, and remaining at least somewhat compliant after implantation. The implant is stored/delivered using a syringe (see entire document).

9. Claims 36-49, 51-68, 70, and 71 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Boyce et al. (US 6,294,187).

Boyce et al. disclose a conformable (it is capable of being conformed to the repair site), multi-phasic implant, said implant comprising/consisting of a plastically deformable (“*capable of being plastically deformed*”: besides comprising plasticizers, the matrix is plastically deformed/compressed into any of various shapes; see columns 4, 7, 8, 11, and 12), tissue conductive matrix, said matrix comprising/consisting of two phases/components, wherein a first phase/component of said matrix comprises/consists of fibers (see column 8, lines 59-65), including insoluble collagen fibers (see column 9, lines 31-33), and a second phase/component of said matrix comprises/consists of flowable collagen gel (e.g., gelatin, soluble collagen; see column 8, lines 13-46), said implant having a consistency of paste/putty (see column 7, lines 21-32; see entire document) prior to implantation, and remaining at least somewhat compliant after implantation. The matrix comprises additives (ceramics: column 8, lines 47-58; demineralized

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bone particles: columns 5-7). Further, the matrix may include biological agents (see column 7, lines 55-65; column 9). The implant is stored/delivered using a syringe-like cylindrical housing (see entire document), which syringe-like cylindrical housings (e.g., cannula) are well known in the art.

***Response to Arguments***

10. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

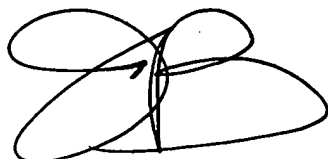
11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Cioca (US 4,412,947), Morganti (US 4,834,734), and Harvey et al. (US 6,001,895).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (9:00 a.m.-6:00 p.m.), first Friday of the bi-week off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB



January 27, 2006



David H. Willse  
Primary Examiner